OMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98 D-0928]

Semiannual Guidance Agenda

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing the first semiannual guidance document agenda. FDA committed to publishing, on a semiannual basis. possible guidance topics or documents for development or revision during the next year, and seeking public comment on additional ideas for new or revisions of existing guidance documents. This commitment was made in FDA's February 1997 ' 'Good Guidance Practices" (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. This list is intended to seek public comment on possible topics for guidance documents and possible revisions to existing guidances.

DATES: Comments on this list and on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

For general information regarding FDA's GGP's contact: Lisa L. Barclay, Office of Policy (HF–22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301-827-3360.

For information regarding specific topics or guidances, please see contact persons listed below.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice announcing its GGP's, which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. The agency adopted the GGP's to ensure public involvement in the development of guidance documents and to enhance public understanding of the availability, nature, and legal effect of such guidance.

As part of FDA's effort to ensure meaningful interaction with the public regarding guidance documents, the agency committed to publishing a semiannual guidance document agenda of possible guidance topics or documents for development or revision during the next year, The agency also committed to soliciting public input regarding these and additional ideas for new topics or revisions to existing guidance documents.

The agency is neither bound by this list of possible topics nor required to issue every guidance document on this list or precluded from issuing guidance documents not on the list set forth in this document.

The following list of guidance topics or documents represents possible new topics or revisions to existing guidance documents that the agency is considering. The agency solicits comments on the topics listed in this document and also seeks additional ideas from the public. On June 1, 1998, the President instructed all Federal agencies to ensure the use of "plain language" in all new documents. As part of this initiative, FDA is also seeking public comment on the clarity of its guidance documents.

The guidance documents are organized by the issuing Center or Office within FDA, and are further grouped by topic categories. The agency's contact persons are listed for each specific area.

II. Center for Biologics Evaluation and Research (CBER)

Title/Topic of Guidance	Contact
CATEGORY--COMPLIANCE AND INSPECTION Guidance for Reprocessing, Reworking, and Blending Practices for Biological Bulk Substances, Final Bulk, and Finished Products.	Stephen M. Ripley, Center for Biologics (HFM-1 7), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

TitleTopic of Guidance	Contact
Guide for Inspection of Blood Banks	Do.
Guide to Inspections of Source Plasma Establishments.	Do.
Compliance Program 7342.002, Inspect[on of Source Plasma Establishments	Do.
Compliance Program 7342.001, Inspections of Licensed and Unlicensed Blood Banks.	Do.
Compliance Program for Inspections of Allergenic Product Manufacturers,	Do
Compliance Program for Inspections of Licensed Therapeutic Products	Do
Guidance for the Design, Installation, and Operations of Water Systems,	Do.
Guidance on Heating, Ventilation, and Air Conditioning (HVAC) and the Monitoring of Environments for the Manufacture of Biological Substances and Products	Do
Guidance for the Validation of the Limulus Amebocyte Lystate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices,	Do
CATEGORY—THERAPEUTICS	
Guidance for the Chemistry, Manufacturing and Control Information on Naturally Derived Proteins.	Do.
Guidance for the Chemistry Manufacturing and Control Information on Gene Therapy Products.	Do.
Guidance on Monoclinal Antibodies and Orphan Drug Designation.	Do.
Guidance to Industry on Xenotransplantation.	)0.
Guidance for Industry Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans.	)0.
Guidance on Clinical Trial Issues in Wound Healing.	)0
CATEGORY—BLOOD AND BLOOD COMPONENTS	
Guidance for Clarification of the December 11, 1996. Memorandum: "Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jacob Disease (CDJ) by Blood and Blood Products. "	)0
Guidance for Collection, Testing and Release of Autologous Blood	Do.
Guidance for Recommendations for Donor Testing by Automated Methods When Using Treponemal Based Screening Tests for Syphilis.	)0.
Guidance for Reviewer Guidance for a Premarket Notification Submission for Automated Blood Establishment Testing Instruments.	)0.
Guidance for Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors.	)0.
Guidance for HIV Reentry Algorithms for Deferred Blood and Plasma Donors.	Do.
Guidance for Chemistry Manufacturing and Control Information on In Vitro Diagnostic Products	)0.
Guidance for Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Xenograft Recipients and Their Close Contacts, Through Whole Blood, Blood Components, Source Plasma, and Source Leukocytes.	Do.
Guidance for Additional Recommendations for Donor Questioning Regarding Travel to Areas Endemic for Malaria.	)0.
Guidance for Platelet Testing and Evaluation of Platelet Substitute Products.	Do.
Guidance for Size Limitations for Human Blood or Plasma Pools Used to Manufacture Injectable Drug Products.	)0.

III. Center for Devices and Radiological Health (CDRH)

Title/Topic of Document	Contact
Guidance on Custom Devices.	Wally Pellerite, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-4692.
Guidance on Medical Device Tracking-Revision (Level 1).	Casper Uldriks, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 5600 Fishers Lane, HFZ-300, Rockville, MD 20857, 301 –594–4692.

Title/Topic of Document	Contact
Guidance on PMA Submissions and Inspectional Quality System Regulation Assessment—Proposal (Level 1).	Wes Morganstern. Center for Devices and Radiological Health (HFZ-305), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-4699.
Guidance on Inspectlon of Medical Device Manufacturers—Proposal (Level 1).	Do
Compliance Policy Guide on Remanufacturing of Used Medical Devices—Draft (Level 1),	Do.
Guidance on Year 2000 Issues for Medical Device Manufacturers and Servicers-Proposal (Level 1).	Stewart Crumpler, Center for Devices and Radiological Health (HFZ-343), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594–4659, or Thomas Shoppe, Center for Devices and Radiological Health (H FZ–140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3314.
Erythropoietin Assay.	Joseph L.Hacket, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-3084.
Fibrin Monomer Paracoagulator Tests.	Do.
Kits for Screening Drugs of Abuse To Be Used by the Consumer	Do,
Assayed and Unassayed Quality Control Material,	Do.
Point of Care In Vitro Diagnostic Devices.	Do.
Extracorporeal Membrane Oxygenators (ECMO).	Lynn A. Reamer, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301 –443–8320.
Compressible Limb Sleeves.	Do.
Thermal Regulating Devices.	Do
Cardiopulmonary Bypass Roller Pumps	Do.
Guidance for Intraaortic Balloon Pumps,	Do.
Cardiac Monitors (including Cardiotachometers and Rate Alarm).	)0.
Electrocardiographs.	Do.
Cardiopulmonary Bypass Nonroller-Type Pumps.	)0.
Annulolasty Rings.	)0.
Vascular Prostheses,	Do.
Cardiopulmonary Bypass Arterial Filters.	)0.
Cardiopulmonary Bypass Defoamers.	)0.
Blood Gas Exchangers (Oxygenators) Used in Cardiopulmonary Bypass.	10.
Endoscopes.	Patricia J. Miller, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301 –594-5072,
Audiometers.	Do.
Assistive Listening Devices.	Do.
Phonosurgery Implants for Vocal Cord Medialization.	Do.
Biocompatibility of Materials in ENT Implants.	Do
Endoscope Sheaths.	Do
Body Composition Analyzers,	Do.
Hemodialysis Blood Access Devices (Level 2).	Do.
Blood Lines for Hemodialysis (Level 2),	Do.
Nasogastric Feeding Tubes (Level 2).	Do.
In Vivo Devices for the Detection of Cervical Cancer and Its Precursors: IDE.	Do
Intrapartum Fetal Pulse Oximeters—IDE/PMA.	Do.
Thermal Endometrial Ablation Systems—IDE/PMA.	Do.
Radiation Therapy Treatment Planning.	Do.
Linear Accelerator,	Do.
Ultrasound Coupling Gel.	Do.
Radionuclide Dose Calibrator.	Do.
Ultrasound Transducer Probe Covers.	Do.
Ultrasound Bone Sonometers.	Do.
Bone Densitometry Device Labeling.	Do.
Emission Computed Tomography System.	Do.
Nuclear Tomography,	Do.
Electrohydraulic Lithotripters.	Do.
Extracorporeal Shockwave Lithotripters.	Do.
Neonatal Incubators and Neonatal Transport Incubators,	Von Nakayama, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-8913,
Spinal Assemblies (IDE's)	Sammie Niver, Center for Devices and Radiological Health (H FZ–41O), Food and Drua Adminjstratian. 5600 Fishers Lane, Rockville, MD 20857, 301 –594–2036.
Ophthalmic Camera	Deborah L, Falls, Center for Devices and Radiological Health, Food and Drug Administration (HFZ–460), 5600 Fishers Lane, Rockville, MD 20857, 301 –594–2205.
Keratome	Do.

Title/Topic of Document	Contact
Refractive Implants	Do
Intraocular Lens Delivery Systems.	Do
Accountability Analysis for Ophthalmic Devices.	Do
Keratoprosthesis.	Do
Glaucoma Drainage.	Do
Nonprescription Sunglasses.	Do
Patient Labeling Guidance (Level 1).	Paula G Silberberg, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-1217.
Human Factors Data To Be Submitted in Premarket Submissions (Level 1).	Ronald D. Kaye, Center for Devices and Radiological Health (HFZ-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-3265
Questions and Answers About the Mammography Quality Standards Act Final Regulations (Level 1).	Kathleen M. Sheridan, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 5600 Fishers Lane, Rockwile, MD 20857, 301–594–3275.
Search Engine to Use With Guidance Documents Developed for Mammography Quality Standards Act (Level 2).	Do.
Guidance for Additional Mammography Review (AMR).	Do.
Guidance for Patient Notification Under Mammography Quality Standards Act.	Do.
MDR Reporting for Manufacturers—Revision.	Thomas E. Cardamone, Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 56 00 Fishers Lane, Rockville, MD 20857, 301–443–0806, ext. 117.
MDR A Brief Overview-Revlslon of Archived Document.	Do.
Registration and Listing instructions—Revmon.	Do.
Registration and Listing Manual—Revision of Archived	Do.
Immunotoxicity Testing.	John J. Langone, Center for Devices and Radiological Health (HFZ–113), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-7132.
Testing for Infant Apnea Monitors (draft).	Jeffrey L Silberberg, Center for Devices and Radiological Health (HFZ–141), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 301–443–2536, ext. 15.
Identification and Evaluation of Candidate Consensus Standards Recognition.	Harvey Rudolph, Center for Devices and Radiological Health (HFZ–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4777.
Guidance to Manufacturers for the Development of Postmarked Surveillance Plans Required Under Section 522 of the Federal Food, Drug, and Cosmetic Act (immediately in effect).	Laura A. Alonge, Center for Devices and Radiological Health (HFZ-543), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301-594-0648.
Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarked Surveillance Requirements (draft).	Do.
Reportability of Incidents Associated With the Use of Endosseous Implants (final).	Do.
Reportability of Incidents Associated With the Use of External Defibrillators (final)	Do.
MDR Questions and Answers.	Do.
Reportability of Incidents Associated With the Use of Implants.	Do.
Reuse of Medical Devices.	Do.
Statistical Guidance for Clinical Trials of Nondiagnostic Devices (revised).	Do.
Statistical Guidance for Clinical Trials of Diagnostic Devices.	Do.
Statistical Guidance on Bayesian Methodsin Medical Device Clinical Trials.	Do.
Guidance for MDR Analysts on Adverse Event Report Review.	Do.
Guidance on MDR Prioritization,	Do.
Guidance for Reviewers of Postmarked Surveillance Submissions.	Do.

IV. Center for Drugs Evaluation and Research (CDER)

Title/Topic of Document	Contact
CATEGORY—ADVERTISING	
Accelerated Approval Products: Submission of Promotional Materials.	Nancy E. Derr, Center for Drug Evaluation and Research (HFD–5), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-594-5400.
Advertising and Labeling of Treatment IND Protocols.	Do.

Title/Topic of Document	Contact
Anti- infective Human Drug and Biological Products Advertising and Promotional Labeling.	Do.
Comparative Claims in Advertising and Labeling.	Do
Fair Balance	Do.
Healthcare Economic Information	Do.
Health Related Quality of Life Claims.	Do.
Infomercials,	Do.
Promotion at International Meetings,	Do.
Promotion of Investigational Products,	Do.
Promotion of Medical Products on the Internet.	Do.
Proprietary (Brand) Name and Established (Generic) Name Placement, Size, and Prominence in Advertising and Promotional Labeling.	Do.
Providing Electronic Submissions to the Division of Drug Marketing, Advertising, and Communications	Do.
CATEGORY—BIOPHARMACEUTICS	
Albuterol Inhalation Aerosols; Revision.	Do.
Bioavailability/Bioequivalence Studies for NDA's and ANDA's-Orally Administered Drugs,	Do.
Bioanalytical Methods Validation: Bioavailability and Bioequivalence Studies Based on Drug or Metabolizes Assay in a Biological Matrix.	Do.
Conjugated Estrogens Tablets: Revision.	Do.
In Vivo Pharmacokinetics and Bioavailability Studies and In Vitro Dissolution Testing for Levothyroxine Sodium Tablets	Do.
Nasal Inhalation Aerosols and Metered Dose Spray Pumps for Local Action.	Do.
Oral Inhalation Drug Products for Local Action, MDI's, DPI's, and Inhalation Solutions.	Do.
Pharmacokinetics Metrics for Bioavailability/Bioequivalence	Do.
Waiver of In Vivo Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms.	Do.
CATEGORY—CHEMISTRY	
Bulk Actives Postapproval Changes (BAC PAK 1) Postapproval CMC Changes Prior to the Final Intermediate.	Do.
Bulk Actives Postapproval Changes (BAC PAK II) Bulk Actives Postapproval Changes, Postapproval Changes From the Final Intermediate to the Drug Substance.	Do.
Botanical Drug Products.	Do.
Changes to an Approved NDA or ANDA Description (21 CFR 314.70; revisions).	Do
Content and Format of IND's for Phases 2 and 3 Studies of New Drugs Including Well-Characterized, Therapeutic, Biotechnology-Derived Products.	Do.
Drug Master Files, General Content and Format.	Do
Environmental Assessment Submissions; Revision.	Do
Formal Meetings With CDER/CBER on Chemistry, Manufacturing and Controls Information for IND Studies, Including on Specified Therapeutic Biotechnology-Derived Products.	Do.
SUPAC Semisolids, Manufacturing Equipment Addendum.	Do.
SUPAC Transdermal Systems, Manufacturing Equipment Addendum	Do.
Methods Validation.	Do.
Monoclinal Antibodies Used as Reagents in Drug Manufacturing, Recommendations on Tests and Specifications.	Do.
NDA's: Impurities in Drug Substances.	Do.
Postapproval Changes for Sterile Aqueous Solutions.	Do.
Proprietary and Established Drug Names.	Do.
Provides Recommendation Regarding Submission of Information for Drug Products Containing Cyclodextrin.	Do.
Submission of Chemistry and Biopharmaceutical Information for Liposomal and Lipid-Complexed Drug Products	Do.
Submission of Chemistry Information on Chiral Drugs.	Do.
Submission of Chemistry, Manufacturing, and Controls Documentation for Inhalation Drug Products: MDI's and DPI's.	Do.
Submission of Documentation for Antibiotics and Other Cellular Metabolizes Produced by Microorganisms Modified by the Use of Recombinant DNA Technology.	Do.
Submitting Manufacturing and Quality Control Information With IND's, NDA's, ANDAs, and AADA's.	Do.
SUPAC Immediate Release; Revision.	Do.
SUPAC Transdermal Systems.	Do.
CATEGORY—CLINICAL ANTIMICROBIAL	
Acute Bacterial Arthritis; Developing Antimicrobial for Treatment.	Do.

Title/Topic of Document	Contact
Opportunistic Infections Related to Aids: Developing Antimicrobials for Treatment,	Do.
Sepsis/Septic Shock, Developing Antimicrobials for Treatment.	Do
Surgical Prophylaxis: Developing Antimicrobial for Treatment	Do.
Antifungal Agents: Developing Antimicrobials for Treatment.	Do.
Antimicrobacterial Agents, Developing Antimicrobial for Treatment,	Do.
Antiparasitic Agents; Developing Antimicrobial for Treatment.	Do.
Antiviral Agents; Developing Antimicrobial for Treatment,	Do.
Complicated Intra-Abdominal Infections; Developing Antimicrobial for Treatment.	Do.
Dermatological Surgical Scrubs; Developing Antimicrobial for Treatment.	Do.
Endocarditis; Developing Antimicrobial for Treatment.	Do.
Gynecologic Infections (Except Sexually Transmitted Disease and Pelvic Inflammatory Disease); Developing Antimicrobial for Treatment.	Do.
Helicobacter Pylori Infections; Developing Antimicrobial for Treatment.	Do.
Immunologic/Transplant Agents; Developing Antimicrobial for Treatment,	Do.
Osteomyelitis (Acute and Chronic); Developing Antimicrobial for Treatment.	Do.
Pelvic Inflammatory Disease: Developing Antimicrobial for Treatment.	Do.
Uncomplicated Intra-Abdominal infections; Developing Antimicrobial for Treatment.	Do.
CATEGORY—CLINICAL MEDICAL	
Assessment of Reproductivity and Developmental Toxicity	Do
Clinical Development of Drugs for the Treatment of Allergic Rhinitis.	Do
Clinical Development of Drugs for the Treatment of Chrome Sinusitis (other than antimicrobials).	Do
Clinical Development Programs for MDI and DPI Drug Products.	Do.
Clinical Evaluation of Lipid-Altenng Agents.	Do
Clinical Evaluation of Potential ECG Effects of New Antihistamines.	Do.
Clinical Evaluation of Weight-Control Drugs.	Do.
Clinical Guidance for Estrogen/Progestin Containing Drug Products.	Do.
Clinical Guidance for Estrogen Drug Products.	Do.
Clinical Trials: Hormone Replacement Therapy in Women.	Do
Content and Format for "Geriatric Use" Supplemental Applications	Do.
Content and Format of the Adverse Reactions Section of the Labeling.	Do.
Content and Format of the Clinical Studies Section of Labeling for Human Drugs and Biologics.	Do.
Content and Review of Applications.	Do,
Developing Clinical Programs for Developing Drugs, Devices, and Biological Products for the Treatment of Systemic Lupus Erythematosus.	Do.
Development of Medical Imaging Products.	Do.
Establishing Pregnancy Registries	Do.
Evaluation of Growth Effects of Orally Inhaled and Intranasal Corticosteroids in Asthma and Allergic Rhinitis.	Do.
Evaluation of New Treatments for Diabetes Mellitus.	Do.
Fast Onset for Analgesic (Rx) Products,	Do.
Fast Track Products: Policies and Procedures.	Do
General Guidance for Eye Allergy Relief/Allergic Conjunctivitis Clinical Trials.	Do.
General Guidance for Glaucoma/IOP Lowering Clinical Trials.	Do.
GRP (Good Review Practices) Guidance: Content and Format of the Clinical Review of a Marketing Application (will be developed in parts).	Do.
GRP Guidance: Safety Review of Clinical Data (1st part of the GRP guidance).	Do.
General Considerations for Pediatric Pharmacokinetic Studies.	Do.
Guidelines for the Clinical Evaluation of Motility Modifying Drugs.	Do.
Guidelines for the Clinical Evaluation of Drugs for Crohn's Disease.	Do.
Guidelines for the Clinical Evaluation of Drugs for Ulcerative Colitis.	Do.
Helicobacter Pylori Ulcers.	Do.
Human Pregnancy Outcome Data.	Do.
LUPUS.	Do.
NSAID Ulcers.	Do.
NSAID GI–Sparing Study Guidance.	Do.
Other Ulcers.	Do.
Pain Claim Structure; Acute Versus Chronic Conditions.	Do.
Pediatric Clinical Trial Design.	Do.
Performance of Clinical Trials for Gastroduodenal Ulcer Disease.	Do.

Title/Topic of Document	Contact
Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products	Do.
Post Cataract Inflammation Studies.	Do.
Preclinical and Clinical Evaluation of Agents Used in the Prevention o Treatment of Postmenopausal Osteoporosis.	Do.
Preclinical Development of Inhalation Drugs for Indications in Children Two Years of Age or Less,	Do.
Psoriasis Therapies.	Do.
Uveitis Studies,	Do.
Removal of a Preservative to Create a Preservative Free Ophthalmic Solution.	Do.
Submission of Debarment Certification Statements and Other Information Under The Generic Drug Enforcement Act of 1992,	Do.
Vaginal Contraceptive Drug Development.	Do.
Wound Care Products.	Do.
CATEGORY—CLINICAL PHARMACOLOGY	
Clinical Pharmacology and Biopharmaceutical Data for Human Drug Products,	Do.
Failed Bioequivalence.	Do.
Format and Content of the Clinical Pharmacology Section of Prescription Drug Product Labeling,	Do.
Immediate Release to Modified Release Dosage Forms.	Do.
In Vitro Drug Metabolism/Drug Interaction.	Do.
In Vivo Drug Metabolism/Drug Interaction	Do.
Pharmacokinetics and Pharmacodynamics.	Do.
Pharmacokinetics in Patients With Impaired Hepatic Function. Study Design, Data Analysis, and Impact on Dosing and Labeling	Do.
Submission of Expanded Synopses for Clinical Pharmacology and Biopharmaceutics Studies	Do
CATEGORY—COMPLIANCE	
Civil Money Penalty Cases Under the Prescription Drug Marketing Act (PDMA).	Do.
Development, Implementation, and Maintenance of a Sample Security and Audit System Under the Prescription Drug and Marketing Act (PDMA).	Do.
Investigating Out of Specification (00S) Results for Pharmaceutical Production.	Do
First Party Audit.	Do.
Plant Readiness; Proapproval Good Manufacturing Practices Inspections.	Do.
Maintaining Adequate and Accurate Records During Clinical Investigations.	)0.
National Drug Code Number and Drug Product Labels.	30.
Sterile Drug Products Produced by Aseptic Processing: Revision.	)0.
Waiver of Informed Consent Requirements for Emergency Care Research.	Do.
CATEGORY—GENERICS	
Changes in Labeling of ANDA's Subsequent to Revisions in the Reference Listed Drug Labeling.	Do.
Clindamycin Intravenous Labeling.	Do.
Office of Generic Drugs, Policy on Inactive Ingredients.	Do.
organization of an Abbreviated New Drug Application; Revision.	Do.
Product Variations Within the Same ANDA,	Do.
Submitting Documentation to Abbreviated Drug Applications for Degradation Products in Drug Products.	Do.
Variations in Drug Product That May Be Included in a Single Application.	Do.
CATEGORY—INFORMATION TECHNOLOGY.	
Computerized Systems Used in Clinical Trials.	Do.
Electronic Submission of Adverse Reaction Data Via Physical Media.	Do.
Providing Regulatory Submissions in Electronic Format (will be completed in parts-the part on the NDA published 9/97).	Do.
Standards for Electronic Safety Data Submissions.	Do.
CATEGORY—LABELING	
Labeling for Combined Oral Contraceptives, Physician Labeling and Instructions for Use.	Do.
Labeling Guidance for Noncontraceptive Estrogen Drug Products.	Do.
Placing the Therapeutic Equivalency Rating on Prescription Drug Labels.	Do.
Topical Corticosteroid Class Labeling,	Do.
CATEGORY—OVER THE COUNTER	
points to Consider for OTC Actual Use Studies; Revision,	Do.

Title/Topic of Document	Contact
CATEGOR!—-PHARMACOLOGV TOXICOLOGY	
Statistical Aspects of Design, Analysis, and Interpretation of Animal Carcinogenicity Studies.	Do.
Testing for Photocarcinogenesis.	Do
CATEGORY—PROCEDURAL	
Appealing Center Regulatory and Scientific Decisions.	Do.
Clarify Requirements for Submission of Supplements.	Do.
Formal Meetings Between CDER and Sponsors and Applicants for PDUFA Products.	Do.
Major Dispute Resolution Involving PDUFA Covered Products.	Do
Regulatory Considerations for section 505(b)(2) of the Federal Food, Drug, and Cosmetict Act Applications.	Do.
Scientific Advisory Panels.	Do.
Special Protocols for the Content and Review of Applications.	Do.
CATEGORY—USER FEES	
Product, Establishment, and Application Fees, Issues and Resolutions.	Do.

V. Center for Veterinary Medicine (CVM)

Title/Topic of Document	Contact
CATEGORY—FOOD ADDITIVES	
Data Requirements for Demonstrating a Food Additive Can Control *Salmonella* in Feed	George Graber, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7500 Standish PI , Rockville, MD 20855, 301-827-6651.
Data Requirements for Demonstratinga FoodAdditiveBindsMycotoxins.	Do.
CATEGORY—MICROBIAL PRODUCTSIN FEEOS	
Compliance Policy Guide About Microbial Products.	Do.
CATEGORY—HUMAN FOOD SAFETY	
Disposition of Animals Used in Research and in the Manufacture of Biomedical Products,	Linda R. Tollefson or Margaret Miller, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish PI Rockvine, MD 20855, 301–827–6644 or 301–594–1620.
Animal Medicinal Drug Use Clarification Act Safe Levels Guidance.	Do.
Metabolism Guidance.	Do.
Threshold Assessment Guidance,	Do.
Tolerance Guidance.	Do
Microbiological Tolerances/Withdrawal Times Guidance,	Do.
Risk Analysis Guidance.	Do.
Animal Drug Availability Act import Tolerance Policy,	Do.
Microbiological Testing of Antimicrobial Drug Residues in Food Guidance.	Do.
CATEGORY—SUBSTANTIAL EVIDENCE	
One versus Multiple Adequate and Well-Controlled Studies/Field Studies.	Herman M. Schoenemann, Ill, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl.,Rockville, MD 20855, 301-827-0220,
Choosing Study Parameters (Direct, Surrogate).	Do.
Inferential Value for Conditions, Animal, and Time,	Do.
Use of Published Studies.	Do.
Use of Foreign Studies.	Do.
Number and Types of Studies (By Drug Class) Needed to Demonstrate Effectiveness.	Do.
Principles of Statistical Analysis Relevant to Regulatory Studies.	Do.
Combination New Animal Drugs.	Do.
Positive Control.	Do.
Dose or Dose Range Characterization.	Do.
CATEGORY—MANUFACTURING CHEMISTRY	
Stability Guidance,	William G. Marnane, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish PI., Rockville, MD 20855, 301–594–0678.
Guidance on Chemistry and Manufacturing Changes and Good Manufacturing Practices Requirements for Minor Use/Minor Species Drug Products.	Do.
CATEGORY—TARGET ANIMAL SAFETY AND EFFECTIVENESS STUDIES FOR PRODUCTION DRUGS.	

Title/Topic of Document	Contact
Anticoccidial in Poultry Guidance	Andrew J. Beaulieu, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1620.
CATEGORY—TARGET ANIMAL SAFETY AND EFFECTIVENESS STUDIES FOR THERAPEUTIC DRUG USES	
Guidance on Recommended Content and Format for Investigational New Animal Drug Data Submissions for HFV–1 10.	Do
Nonsteroidal Anti-inflammatory Drug Guidance.	Do.
Competitive Exclusion Guidance.	Do.
CATEGORY—OTHER PREMARKETING	
Bioequivalence of Continual Release Drugs Such as Implant Drugs.	Do.
Correlation of InVitro Dissolution and InVivo Bioavailability.	Do.
FOI Summary Guidance.	Do.
CATEGORY—STATISTICS	
Add Log C l Guidance to Bioequivalence Guidance.	Anna B. Nevius, Center for Veterinary Medicine (HFV–124), Food and Drug Administration, 7500 Standish Pi., Rockville, MD20855,301-827-0218.
General Statistical Procedures for Designing and Analyzing Research.	Do.
Alternative Methods,	Do.

VI. Office of Regulatory Affairs (ORA)

Title/Topic of Document	Contact
CATEGORY—COMPLIANCE POLICY GUIDES	
Compliance Policy Guide, Chapter 1, Sec. 140.100, Seizure of Books That Constitute Misleading Labeling (CPG 7153.13).	JoAnne C. Marrone, Division of Compliance Policy (H FC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1242.
Compliance Policy Guide, Chapter5, Sec. 540.400, Shrimp-Fresher Frozen, Raw, Headless, Peeled or Breaded—Adulteration Involving Decomposition (CPG 7108.11).	MaryLynn A. Datoc, Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827-0413.
Compliance Policy Guide, Chapter 5, Sec. 540.650, Sale-Cured, Air-Dried, Uneviscerated Fish (e.g., "Kapchunka") (CPG 7108. 17).	Do.
Compliance Policy Guide, Chapter 6, Sec. 675.400, Rendered Animal Feed Ingredients (CPG 7126.24).	Barbara A. Rodgers, Division of Compliance Policy (H FC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-8270417,
Compliance Policy Guide: Evaluation and Processing of Post Donation Reports.	JoAnne A. Marrone, Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301 –827–1 242,
Compliance Policy Guide: Summary of Records Accompanying Human Tissue for Transplantation.	Do.
Compliance Policy Guide: Foods Contaminated With Hard or Sharp Foreign Objects.	MaryLynn A. Datoc
CATEGORY—COMPLIANCE PROGRAMS; BIORESEARCH MONITORING	
Compliance Program 7348.808, Bioresearch Monitoring; Good Laboratory Practices (GLP) (Nonclinical),	James F. McCormack, Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0425.
Food Laboratory Practice Program (Nonclinical Laboratories) 7348.808A: EPA Data Audit Inspections.	Do.
Compliance Program 7348.810: Sponsors, Contract Research Organizations and Monitors.	Do.
Compliance Program 7348.809: Bioresearch Monitoring; Institutional Review Board,	Do.
Compliance Program 7348,811: Bioresearch Monitoring; Clinical Investigations.	Do
CATEGORY—INSPECTION GUIDES	
Guide to Inspections of Source Plasma Establishments.	Elizabeth A. Waltrip, Division of Emergency and Investigational Operations (HFC–132), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 301–827–5662.
CATEGORY—LABORATORY PROCEDURES MANUAL	
Laboratory Procedures Manual, Chapter 1, Sample Accountability.	Leonard Valenti, Division of Field Science (HFC–140), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443-71 03.
Laboratory Procedures Manual, Chapter 10, Research Guidelines	Lawrence D'Hoostelaere, Division of Field Science (H FC–140), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3320.

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William K. Hubbard
Associate Commissioner for Policy Coordination

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